Breaking Implicit Bias Habits: An Individuation Pilot Study in Rheumatology

Principal Investigator: Candace Feldman, MD

Identifier: NCT05116163

Patient consent form date: June 14, 2023

Protocol Title: Breaking Implicit Bias Habits: An Individuation Pilot to Promote Equity in Rheumatic Disease Care

Principal Investigator: Candace Feldman, MD, ScD

Site Principal Investigator: N/A

Description of Subject Population: English-speaking adults with lupus, osteoarthritis, or inflammatory arthritis including rheumatoid arthritis who identify as Black/African American or who are insured by Medicaid/Mass Health and receive care from a rheumatologist at BWH or MGH.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

The purpose of this pilot study to understand the quality of rheumatology care provided to patients with lupus, osteoarthritis, and inflammatory arthritis including rheumatoid arthritis and whether certain strategies to reduce unconscious bias may improve the care provided.

How long will you take part in this research study?

If you decide to join this research study, the majority of your participation will occur on one day that will coincide with your next rheumatology appointment. Three months later, you will also be asked to complete a single 3-5-minute survey about your medication use, and we will review your electronic medical record for the 6 months after your encounter with your rheumatologist.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

1) You will be asked to allow us to audio-record your visit with your physician. Your physician has also been asked to participate in this study and will be specifically asked again for his/her consent to allow us to record the visit.
2) You will complete a set of surveys after the visit and then a single short survey 3 months later.
3) We will review your medical record for the 6 months after you enroll to look at your clinical notes, your medications, whether you've had certain tests and your health care use (such as whether or not you needed to go to the hospital).

Why might you choose to take part in this study?

We are hoping to better understand how to improve communication between physicians and patients, how to reduce possible unconscious biases of physicians, and ways to improve the care physicians provide to their patients. You will not benefit directly from taking part in this research study, but both patients and physicians may benefit in the future from what we learn in this study. We will de-identify all of your data (meaning that we will remove all ways of identifying that it is you or your physician) when we conduct our analyses.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. Important risks and possible discomforts to know about include breach of confidentiality. A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?" Other things to consider are your willingness to have your visit audio-recorded and the time associated with taking the surveys.

What other treatments or procedures are available for your condition?

Your rheumatologist or primary care physician is currently prescribing medication to treat your rheumatic condition. You should continue to take these medications and do not have to participate in this study to be treated. Your participation will have no direct impact on the treatments or procedures you receive.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Candace Feldman MD, ScD is the person in charge of this research study. You can call her at **617-525-1035 M-F 9-5.** You can also call **Greta Sirek**, the research assistant, at **(617) 525-9662 M-F 9-5** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Greta Sirek** at **(617) 525-9662 M-F 9-5**.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

The purpose of this study is to understand the quality of rheumatology care provided to patients with lupus, osteoarthritis, and inflammatory arthritis including rheumatoid arthritis and whether certain strategies to reduce unconscious bias may improve the care provided. Unconscious biases are stereotypes that people may have about others that they may not even realize they have. We are asking you to allow us to audio-record your visit and to complete several surveys.

Who will take part in this research?

We are asking you to take part in this research study because you are at least 18 years of age, you are diagnosed with a rheumatic condition (inflammatory arthritis, osteoarthritis, rheumatoid arthritis, lupus), and you identify as Black/African American and/or are insured by Medicaid/Mass Health. We expect that up to 200 patients will participate in this study at BWH and MGH. The National Institute on Aging (NIA) is paying for this research to be done.

What will happen in this research study?

If you decide to join this research study, you will be asked to allow us to audio-record your visit with your rheumatologist. The rheumatologists in this study will be randomly assigned to one of two different training arms where they will receive information about unconscious biases. Following your visit with your rheumatologist, we will ask you to take a few surveys either in paper form or electronically using a secure REDCaps tool, to measure your perceptions of and satisfaction with your care. We estimate that this will approximately 15 minutes. One survey also will briefly ask you about how you take your medications both right after the visit and 3 months later. This survey will take no more than 5 minutes. We will also look at your medical record for the 6 months after you agree to participate to understand aspects of the care you receive and to understand general information about your health.

We have a research collaborator at Virginia Commonwealth University who is an expert in this area of research. She will participate in the analyses of data that will include yours, however all identifying information will be removed before this happens. A transcript of the audio recording

will be shared with our collaborator, but the recording itself will not be shared. We will label all your study information with a code number instead of your name. The key to the code connects your name to your study information. We will keep the key to the code here at MGB. No one outside MGB will know which information and/or samples are yours.

How may we use and share your samples and health information for other research?

Information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

At the end of the study (approximately 6-9 months after you agree to participate), we will share with you your survey results and what they mean. We will also share the overall study findings with the rheumatologists at our hospital and publish what we learn in medical journals, but this will include no identifiable information.

What are the risks and possible discomforts from being in this research study?

The risk of this study is breach of confidential health and survey information. However, we will take steps to protect this information so that the risk to your privacy is minimal. Study materials are not labeled with information that will directly identify you. The only people with access to your name, phone number and address are the principal investigator and study staff designated by the principal investigator. Your study results are identified only by a code number generated for this study. Any paper forms will be kept in locked file cabinets.

It is also possible that some of the survey questions may cause you to think about topics that are upsetting to you. If this is the case, and you wish to speak with someone, please let us know and we will have resources available to you. There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

You should not expect to gain any direct benefit from taking part in this study. You may find that answering the surveys may help you better communicate your needs and any problems you have with your rheumatologist.

What other treatments or procedures are available for your condition?

You should continue to follow the directions your rheumatologist gives to you regarding your treatments, tests and medications and do not have to participate in this study to be treated. There will be no specific treatments or procedures offered as part of this study.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive. We would like to emphasize whether you choose to participate or not, it will have no effect on the quality of your care and there are no consequences to participation. We only aim to make the clinical experience better and to understand your unique perspective and experience.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will receive a $30 gift card or e-check at the end of your participation.

What will you have to pay for if you take part in this research study?

We do not anticipate any additional costs to you from participation in this research study.

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on

various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: V8 May 30, 2023

Breaking Implicit Bias Habits: An Individuation Pilot Study in Rheumatology

Principal Investigator: Candace Feldman, MD

Identifier: NCT05116163

Provider consent form date: March 22, 2023

Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: February 2021

Subject Identification

Protocol Title: Breaking Implicit Bias Habits: An Individuation Pilot to Promote Equity in Rheumatic Disease Care

Principal Investigator: Candace Feldman, MD, ScD

Site Principal Investigator: N/A

Description of Subject Population: Rheumatologists at BWH or MGH with >=1 clinics per week

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Mass General Brigham now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

The purpose of this pilot study to understand whether providers (analyzed in aggregate, and de-identified) unintentionally exhibit unconscious bias in their interactions with and care for patients

who are racially discordant or of low socioeconomic status. We are assessing whether different strategies may improve communication and care and reduce reliance on these biases.

How long will you take part in this research study?

If you decide to join this research study, it will take you 4-6 months to complete the study, depending on the frequency of your appointment visits. During this time, we will audio record 8-10 patient encounters at your BWH, FH or MGH rheumatology clinics and review charts of another sample of patients you care for during this period.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen:

1) You will take Implicit Association Tests, measures of unconscious bias, at the beginning and end of the study and a brief demographic survey at the beginning; these tests will be de-identified and the study PIs will not be able to link them back to the provider.
2) You will complete a brief educational training about unconscious bias and possibly, a brief conversation with a study team member regarding strategies to reduce bias in a clinical encounter.
3) You will be randomized into one of two intervention arms.
4) You will be asked to allow us to audio-record your visits with 8-10 patients from whom we will obtain informed consent.
5) We will review medical records of patients who are racially discordant from you during the study period to examine quality of care metrics.

Why might you choose to take part in this study?

Your participation, combined with the participation of other providers, will help us understand the ways in which unconscious bias may contribute to the quality of care patients receive and to provider-patient communication, as well as strategies that may help reduce this impact. It will also help us more broadly consider strategies to help physicians across MGB address their biases in their care for patients.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. Important risks and possible discomforts to know about include breach of

confidentiality. A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are your willingness to have your visits audio-recorded and the time associated with taking the Implicit Association Tests, the demographic survey, and the training. There is a small risk to confidentiality however all data will be de-identified and analyzed in aggregate, and the study PI (Dr. Feldman) and site PIs (Drs. Schoenfeld (MGH) and Dr. Todd (FH)) will be blinded to this deidentification process. If unconscious bias is found in aggregate across providers, individual providers will not be identified but rather, Division and Department of Medicine-wide strategies to help reduce these biases will be implemented.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Candace Feldman MD, ScD is the person in charge of this research study. You can call him/her at **617-525-1035 M-F 9-5.** You can also call **Sciaska Ulysse**, the research assistant, at **617) 264-5907 M-F 9-5** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Sciaska Ulysse** at **(617) 264-5907 M-F 9-5.**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

The purpose of this pilot study to understand whether providers (analyzed in aggregate, and de-identified) unintentionally exhibit unconscious bias in their interactions with and care for patients who are racially discordant or of low socioeconomic status. We are assessing whether different strategies may improve communication and care and reduce reliance on these biases.

Who will take part in this research?

We are asking you to take part in this research study because you are a rheumatologist providing care to patients at MGB. We expect that up to 20 rheumatologists will participate in this study. The National Institute on Aging (NIA) is paying for this research to be done.

What will happen in this research study?

If you decide to join this research study, you will be randomized to one of two arms. You will be asked to take four Implicit Association Tests (IATs), which will take approximately 5 minutes each, and a 5 minute demographics survey, and complete a brief training on unconscious bias (of which you can claim continuing medical education (CME) credit for bias training that will be required as of June 1 for the Massachusetts medical license renewal, total of ~30 minutes) and possibly, to participate in a 10-minute conversation with one of the study team members about ways to reduce unconscious bias. You may be asked to include a brief sentence in your clinical encounters based on an approximately 2-minute conversation with your patient, depending on the arm you are randomized to. You may also receive a weekly reminder to do this. Approximately 1 month later, if your patients provide consent, 8-10 encounters with patients who are racially/ethnically discordant from you, or low socioeconomic status will be audio-recorded. However, immediately before each audiorecorded patient encounter, you will be given permission to opt-out of that specific recording. If you choose to opt-out from an audiorecording, we will document the demographic information for that patient but will not record the encounter. We will also review charts of other patients you care for with lupus, osteoarthritis, and inflammatory arthritis including RA during the study period. After 6 months, you will be asked to repeat the IATs.

We have a research collaborator at Virginia Commonwealth University who is an expert in this area of research. She will participate in the analyses of aggregated, de-identified data that will include yours and your patients, however all identifying information will be removed before this happens. A transcript of the audio recording will be shared with our collaborator, but the recording itself will not be shared. We will label all your study information with a code number instead of your name. The key to the code connects your name to your study information. We will keep the key to the code here at MGB. No one outside MGB will know which information and/or samples are yours.

How may we use and share your samples and health information for other research?

Information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

At the end of the study, since all data will be de-identified and analyzed in aggregate, we will not provide you with your individual Implicit Association Test scores or our findings with your patients since we do not plan to link these data with identifiers. Rather, we will present our overall findings from this pilot study in aggregate at the end of the study as part of a joint BWH-MGH Grand Rounds.

What are the risks and possible discomforts from being in this research study?

The risk of this study is breach of confidential health and survey information. However, we will take steps to protect this information so that the risk to your privacy is minimal. Study materials are not labeled with information that will directly identify you. The only people with access to your name, phone number and address are the study staff designated by the principal

investigator. The PI and site PIs will not be able to link you to your data. Your study results are identified only by a code number generated for this study. Any paper forms will be kept in locked file cabinets. It is also possible that some of the survey questions may cause you to think about topics that are upsetting to you, such as learning about your own biases. If this is the case, and you wish to speak with someone, please let us know and MGB has resources readily available to you and we will help connect you. There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

You should not expect to gain any direct benefit from taking part in this study. You may find that your participation may help you better communicate with your patients and think about ways in which your own unintentional biases may impact your interactions.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You receive $50 in the form of a gift card or e-check for your participation.

What will you have to pay for if you take part in this research study?

We do not anticipate any additional costs to you from participation in this research study.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: V10 March 17, 2023